



April 18, 2019

Dear Requester,

The attached record(s) are being provided by the Office of Regulatory Affairs (ORA) Division of Information Disclosure Policy – Los Angeles District office in response to your request **2019-3334** for record(s) from the Food and Drug Administration pursuant to the Freedom of Information Act regarding:

DR KANG ZHANG, LA JOLLA, CA - 483 6/1/16 TO 1/31/17. Records attached: EIR/FD483 7/14-8/1/16. Your request is granted in part.

After a thorough review of the responsive records, we have determined that portions of the documents are exempt from disclosure under FOIA exemptions (b)(4) of the FOIA 5 U.S.C. § 552, as amended and delineated below:

- Exemption (b)(4) permits the withholding of “trade secrets” (TS) and “commercial confidential information” (CCI). Disclosure of this information would impair the government’s ability to obtain necessary information in the future and cause substantial harm to the competitive position of the person from whom the information was obtained. Under the balancing test of this exemption, we are withholding all proprietary information identified as TS and CCI.
- Exemption (b)(6) permits the withholding of information which, if released, would constitute a clearly unwarranted invasion of personal privacy. In this case, it was determined that there is no countervailing public interest qualifying under the standard set forth, under exemption (b)(6), to release the personal identifying information of certain third parties.

The Los Angeles District office considers your request closed. If you have any questions about this response, you may contact Sandra Williams at 949.608.4466 or sandraa.williams@fda.hhs.gov.

You have the right to appeal this determination. By filing an appeal, you preserve your rights under FOIA and give the agency a chance to review and reconsider your request and the agency’s decision. Your appeal must be mailed within 90 days from the date of this response, to:

Agency Chief FOIA Officer
U.S. Department of Health and Human Services
Office of the Assistant Secretary for Public Affairs
Room 729H
200 Independence Avenue, S.W.
Washington, DC 20201
E-mail FOIARequest@PSC.hhs.gov.

Please clearly mark both the envelope and your letter or email “FDA Freedom of Information Act Appeal.”

If you would like to discuss our response before filing an appeal to attempt to resolve your dispute without going through the appeals process, please contact Sandra Williams at the number or email provided above. You may also contact the FDA Public Liaison for assistance at:

Office of the Executive Secretariat
U.S. Food & Drug Administration
5630 Fishers Lane, Room 1050
Rockville, MD 20857
E-mail: FDAFOIA@fda.hhs.gov

If you are unable to resolve your FOIA dispute through our FOIA Public Liaison, the Office of Government Information Services (OGIS), the Federal FOIA Ombudsman’s office, offers mediation services to help resolve **FOIA**

U.S. Food and Drug Administration
5630 Fishers Lane, Room 1035
Rockville, MD 20857
www.fda.gov



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disputes between FOIA requesters and Federal agencies. The contact information for OGIS is as follows:

Office of Government Information Services
National Archives and Records Administration
8601 Adelphi Road—OGIS
College Park, MD 20740-6001
Telephone: 202-741-5770
Toll-Free: 1-877-684-6448
E-mail: ogis@nara.gov

Please do not submit payment until you receive an invoice. The following charges for this request to date may be included in a monthly invoice:

Reproduction=\$0.00. Search=\$23.00 Review=\$23.00. Other=\$0.00 Total=\$46.00.

Sincerely,

Sandra Williams

Information Disclosure Officer
U.S. Food & Drug Administration
Office of Regulatory Affairs
Office of Strategic Planning and Operational Policy
Division of Information Disclosure Policy
Los Angeles District
Sandraa.williams@fda.hhs.gov
949.608.4466 MAIN
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